US009848956B2

(12) **United States Patent**
Field et al.

(10) **Patent No.: US 9,848,956 B2**
(45) **Date of Patent: Dec. 26, 2017**

(54) **SELF-CONTAINED, SELF-PIERCING, SIDE-EXPELLING MARKING APPARATUS**

(71) Applicants: **Bard Peripheral Vascular, Inc.**, Tempe, AZ (US); **BARD SHANNON LIMITED**, Nieuwegein (NL)

(72) Inventors: **Steven E. Field**, Grand Rapids, MI (US); **Ryan L. Goosen**, Caledonia, MI (US); **Brian R. Mulder**, Rockford, MI (US); **Richard M. Chesbrough**, Bloomfield Hills, MI (US)

(73) Assignees: **Bard Peripheral Vascular, Inc.**, Tempe, AZ (US); **Bard Shannon Limited**, Nieuwegein (NL)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **15/381,717**

(22) Filed: **Dec. 16, 2016**

(65) **Prior Publication Data**

US 2017/0100203 A1 Apr. 13, 2017

Related U.S. Application Data

(60) Division of application No. 15/078,847, filed on Mar. 23, 2016, which is a continuation of application No. (Continued)

(51) **Int. Cl.**
A61B 90/00 (2016.01)

(52) **U.S. Cl.**
CPC ***A61B 90/39*** (2016.02); *A61B 2090/3908* (2016.02); *A61B 2090/3987* (2016.02)

(58) **Field of Classification Search**
CPC A61B 90/39; A61B 2090/3987; A61B 2090/3908
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,899,362 A 8/1959 Sieger, Jr. et al.
2,907,327 A 10/1959 White
(Continued)

FOREIGN PATENT DOCUMENTS

DE 1029528 B 5/1958
EP 0146699 A1 7/1985
(Continued)

OTHER PUBLICATIONS

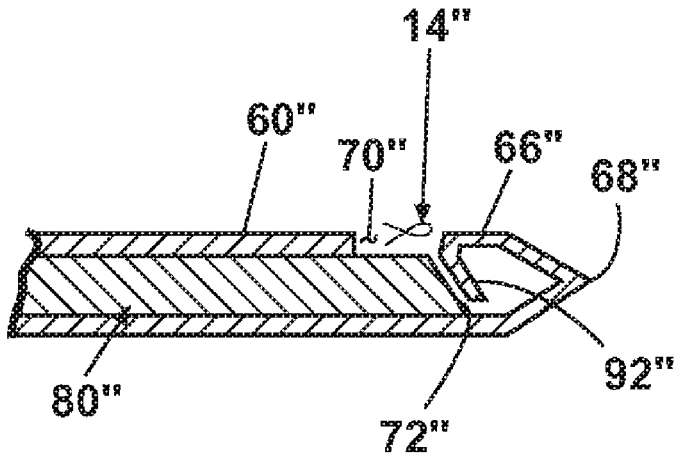
Press release for Biopsys Ethicon Endo-Surgery (Europe) GmbH; The Mammotome Vacuum Biopsy System. From: http://www.medicine-news.com/articles/devices/mammotome.html. 3 pages.
(Continued)

Primary Examiner — Rene Towa

(57) **ABSTRACT**

A marking apparatus includes a rigid cannula having a peripheral wall forming a lumen that carries an imaging marker. A lateral opening in the peripheral wall is open to the lumen. The lateral opening has a proximal extent and a distal extent. A closed-off distal portion is distal to the lateral opening. A resilient end wall extends downwardly from the peripheral wall at the distal extent of the lateral opening. A stylet has a distal end having a ramp. The stylet is slidably received within the lumen of the rigid cannula for movement in the lumen. The resilient end wall of the rigid cannula is configured to engage the ramp of the distal end of the stylet when the stylet is advanced through the lumen of the rigid cannula to an extended position to substantially close off the lateral opening of the rigid cannula.

14 Claims, 5 Drawing Sheets



Related U.S. Application Data

12/850,844, filed on Aug. 5, 2010, now abandoned, which is a continuation of application No. 11/275,918, filed on Feb. 3, 2006, now Pat. No. 7,819,820, which is a continuation of application No. 10/710,587, filed on Jul. 22, 2004, now abandoned, and a continuation-in-part of application No. 10/707,044, filed on Nov. 17, 2003, now Pat. No. 7,424,320.

(60) Provisional application No. 60/427,048, filed on Nov. 18, 2002.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,005,457	A	10/1961	Millman	
3,128,744	A	4/1964	Jefferts et al.	
3,402,712	A	9/1968	Eisenhand	
3,516,412	A	6/1970	Ackerman	
3,818,894	A	6/1974	Wichterle et al.	
3,820,545	A	6/1974	Jefferts	
3,823,212	A	7/1974	Chvapil	
3,921,632	A	11/1975	Bardani	
4,005,699	A	2/1977	Bucalo	
4,007,732	A	2/1977	Kvavle et al.	
4,041,931	A	8/1977	Elliott et al.	
4,086,914	A	5/1978	Moore	
4,103,690	A	8/1978	Harris	
4,105,030	A	8/1978	Kercso	
4,127,774	A	11/1978	Gillen	
4,172,449	A	10/1979	LeRoy et al.	
4,197,846	A	4/1980	Bucalo	
4,217,889	A	8/1980	Radovan et al.	
4,228,799	A	10/1980	Anichkov et al.	
4,276,885	A	7/1981	Tickner et al.	
1,294,241	A	10/1981	Miyata	
4,298,998	A	11/1981	Naficy	
4,331,654	A	5/1982	Morris	
4,347,234	A	8/1982	Wahlig et al.	
4,390,018	A	6/1983	Zukowski	
4,400,170	A	8/1983	McNaughton et al.	
4,401,124	A	8/1983	Guess et al.	
4,405,314	A	9/1983	Cope	
4,428,082	A	1/1984	Naficy	
4,438,253	A	3/1984	Casey et al.	
4,442,843	A	4/1984	Rasor et al.	
4,470,160	A	9/1984	Cavon	
4,487,209	A	12/1984	Mehl	
4,545,367	A	10/1985	Tucci	
4,582,061	A	4/1986	Fry	
4,582,640	A	4/1986	Smestad et al.	
4,588,395	A	5/1986	Lemelson	
4,597,753	A	7/1986	Turley	
4,647,480	A	3/1987	Ahmed	
4,655,226	A	4/1987	Lee	
4,661,103	A	4/1987	Harman	
4,682,606	A	7/1987	DeCaprio	
4,693,237	A	9/1987	Hoffman et al.	
4,718,433	A	1/1988	Feinstein	
4,740,208	A	4/1988	Cavon	
4,762,128	A	8/1988	Rosenbluth	
4,813,062	A	3/1989	Gilpatrick	
4,820,267	A	4/1989	Harman	
4,832,680	A	5/1989	Haber et al.	
4,832,686	A	5/1989	Anderson	
4,847,049	A	7/1989	Yamamoto	
4,863,470	A	9/1989	Carter	
4,870,966	A	10/1989	Dellon et al.	
4,874,376	A	10/1989	Hawkins, Jr.	
4,889,707	A	12/1989	Day et al.	
4,909,250	A	3/1990	Smith	
4,938,763	A	7/1990	Dunn et al.	
4,950,234	A	8/1990	Fujioka et al.	
4,950,665	A	8/1990	Floyd	
4,963,150	A	10/1990	Brauman	
4,970,298	A	11/1990	Silver et al.	
4,989,608	A	2/1991	Ratner	
4,994,013	A	2/1991	Suthanthiran et al.	
4,994,028	A	2/1991	Leonard et al.	
5,012,818	A	5/1991	Joishy	
5,013,090	A	5/1991	Matsuura	
5,018,530	A	5/1991	Rank et al.	
5,035,891	A	7/1991	Runkel et al.	
5,059,197	A	10/1991	Urie et al.	
5,081,997	A	1/1992	Bosley, Jr. et al.	
5,108,421	A	4/1992	Fowler	
5,120,802	A	6/1992	Mares et al.	
5,125,413	A	6/1992	Baran	
5,137,928	A	8/1992	Erbel et al.	
5,141,748	A	8/1992	Rizzo	
5,147,295	A	9/1992	Stewart	
5,147,307	A	9/1992	Gluck	
5,147,631	A	9/1992	Glajch et al.	
5,162,430	A	11/1992	Rhee et al.	
5,163,896	A	11/1992	Suthanthiran et al.	
5,195,540	A	3/1993	Shiber	
5,197,482	A	3/1993	Rank et al.	
5,199,441	A	4/1993	Hogle	
5,201,704	A	4/1993	Ray	
5,219,339	A	6/1993	Saito	
5,221,269	A	6/1993	Miller et al.	
5,234,426	A	8/1993	Rank et al.	
5,236,410	A	8/1993	Granov et al.	
5,242,759	A	9/1993	Hall	
5,250,026	A	10/1993	Ehrlich et al.	
5,271,961	A	12/1993	Mathiowitz et al.	
5,273,532	A	12/1993	Niezink et al.	
5,280,788	A	1/1994	Janes et al.	
5,281,197	A	1/1994	Arias et al.	
5,281,408	A	1/1994	Unger	
5,282,781	A	2/1994	Liprie	
5,284,479	A	2/1994	de Jong	
5,289,831	A	3/1994	Bosley	
5,290,310	A	3/1994	Makower et al.	
5,312,435	A	5/1994	Nash et al.	
5,320,100	A	6/1994	Herweck et al.	
5,320,613	A	6/1994	Houge et al.	
5,328,955	A	7/1994	Rhee et al.	
5,334,216	A	8/1994	Vidal et al.	
5,334,381	A	8/1994	Unger	
5,344,640	A	9/1994	Deutsch et al.	
5,353,804	A	10/1994	Kornberg et al.	
5,354,623	A	10/1994	Hall	
5,358,514	A	10/1994	Schulman et al.	
5,360,416	A *	11/1994	Ausherman	A61B 17/3401 604/158
5,366,756	A	11/1994	Chesterfield et al.	
5,368,030	A	11/1994	Zinreich et al.	
5,388,588	A	2/1995	Nabai et al.	
5,394,875	A	3/1995	Lewis et al.	
5,395,319	A	3/1995	Hirsch et al.	
5,405,402	A	4/1995	Dye et al.	
5,409,004	A	4/1995	Sloan	
5,417,708	A	5/1995	Hall et al.	
5,422,730	A	6/1995	Barlow et al.	
5,425,366	A	6/1995	Reinhardt et al.	
5,431,639	A	7/1995	Shaw	
5,433,204	A	7/1995	Olson	
5,449,560	A	9/1995	Antheunis et al.	
5,451,406	A	9/1995	Lawin et al.	
5,458,643	A	10/1995	Oka et al.	
5,460,182	A	10/1995	Goodman et al.	
5,469,847	A	11/1995	Zinreich et al.	
5,475,052	A	12/1995	Rhee et al.	
5,490,521	A	2/1996	Davis et al.	
5,494,030	A	2/1996	Swartz et al.	
5,499,989	A	3/1996	LaBash	
5,507,807	A	4/1996	Shippert	
5,508,021	A	4/1996	Grinstaff et al.	
5,514,085	A	5/1996	Yoon	
5,522,896	A	6/1996	Prescott	
5,538,726	A	7/1996	Order	
5,542,915	A	8/1996	Edwards et al.	
5,545,180	A	8/1996	Le et al.	

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,549,560	A	8/1996	Van de Wijdeven
5,567,413	A	10/1996	Klaveness et al.
RE35,391	E	12/1996	Brauman
5,580,568	A	12/1996	Greff et al.
5,585,112	A	12/1996	Unger et al.
5,611,352	A	3/1997	Kobren et al.
5,626,611	A	5/1997	Liu et al.
5,628,781	A	5/1997	Williams et al.
5,629,008	A	5/1997	Lee
5,636,255	A	6/1997	Ellis
5,643,246	A	7/1997	Leeb et al.
5,646,146	A	7/1997	Faarup et al.
5,651,772	A	7/1997	Arnett
5,657,366	A	8/1997	Nakayama
5,665,092	A	9/1997	Mangiardi et al.
5,667,767	A	9/1997	Greff et al.
5,669,882	A	9/1997	Pyles
5,673,841	A	10/1997	Schulze et al.
5,676,146	A	10/1997	Scarborough
5,676,925	A	10/1997	Klaveness et al.
5,688,490	A	11/1997	Tournier et al.
5,690,120	A	11/1997	Jacobsen et al.
5,695,480	A	12/1997	Evans et al.
5,702,128	A	12/1997	Maxim et al.
5,702,682	A	12/1997	Thompson
5,702,716	A	12/1997	Dunn et al.
5,716,981	A	2/1998	Hunter et al.
5,747,060	A	5/1998	Sackler et al.
5,752,974	A	5/1998	Rhee et al.
5,762,903	A	6/1998	Park et al.
5,769,086	A	6/1998	Ritchart et al.
5,776,496	A	7/1998	Violante et al.
5,779,647	A	7/1998	Chau et al.
5,782,764	A	7/1998	Werne
5,782,771	A	7/1998	Hussman
5,782,775	A	7/1998	Milliman et al.
5,795,308	A	8/1998	Russin
5,799,099	A	8/1998	Wang et al.
5,800,362	A	9/1998	Kobren et al.
5,800,389	A	9/1998	Burney et al.
5,800,445	A	9/1998	Ratcliff et al.
5,800,541	A	9/1998	Rhee et al.
5,817,022	A	10/1998	Vesely
5,820,918	A	10/1998	Ronan et al.
5,821,184	A	10/1998	Haines et al.
5,823,198	A	10/1998	Jones et al.
5,824,042	A	10/1998	Lombardi et al.
5,824,081	A	10/1998	Knapp et al.
5,826,776	A	10/1998	Schulze et al.
5,830,178	A	11/1998	Jones et al.
5,830,222	A	11/1998	Makower
5,842,477	A	12/1998	Naughton et al.
5,842,999	A	12/1998	Pruitt et al.
5,845,646	A	12/1998	Lemelson
5,846,220	A	12/1998	Elsberry
5,851,508	A	12/1998	Greff et al.
5,853,366	A	12/1998	Dowlatshahi
5,865,806	A	2/1999	Howell
5,869,080	A	2/1999	McGregor et al.
5,871,501	A	2/1999	Leschinsky et al.
5,876,340	A	3/1999	Tu et al.
5,879,357	A	3/1999	Heaton et al.
5,891,558	A	4/1999	Bell et al.
5,897,507	A	4/1999	Kortenbach et al.
5,902,310	A	5/1999	Foerster et al.
5,911,705	A	6/1999	Howell
5,916,164	A	6/1999	Fitzpatrick et al.
5,921,933	A	7/1999	Sarkis et al.
5,922,024	A	7/1999	Janzen et al.
5,928,626	A	7/1999	Klaveness et al.
5,928,773	A	7/1999	Andersen
5,941,439	A	8/1999	Kammerer et al.
5,941,890	A	8/1999	Voegele et al.
5,942,209	A	8/1999	Leavitt et al.
5,948,425	A	9/1999	Janzen et al.
5,954,670	A	9/1999	Baker
5,972,817	A	10/1999	Haines et al.
5,976,146	A	11/1999	Ogawa et al.
5,980,564	A	11/1999	Stinson
5,989,265	A	11/1999	Bouquet De La Joliniere et al.
6,015,541	A	1/2000	Greff et al.
6,027,471	A	2/2000	Fallon et al.
6,030,333	A	2/2000	Sioshansi et al.
6,053,925	A	4/2000	Barnhart
6,056,700	A	5/2000	Burney et al.
6,066,122	A	5/2000	Fisher
6,066,325	A	5/2000	Wallace et al.
6,071,301	A	6/2000	Cragg et al.
6,071,310	A	6/2000	Picha et al.
6,071,496	A	6/2000	Stein et al.
6,090,996	A	7/2000	Li
6,096,065	A	8/2000	Crowley
6,096,070	A	8/2000	Ragheb et al.
6,106,473	A	8/2000	Violante et al.
6,117,108	A	9/2000	Woehr et al.
6,120,536	A	9/2000	Ding et al.
6,135,993	A	10/2000	Hussman
6,142,955	A	11/2000	Farascioni et al.
6,159,240	A	12/2000	Sparer et al.
6,159,445	A	12/2000	Klaveness et al.
6,161,034	A	12/2000	Burbank et al.
6,162,192	A	12/2000	Cragg et al.
6,166,079	A	12/2000	Follen et al.
6,173,715	B1	1/2001	Sinanan et al.
6,174,330	B1	1/2001	Stinson
6,177,062	B1	1/2001	Stein et al.
6,181,960	B1	1/2001	Jensen et al.
6,183,497	B1	2/2001	Sing et al.
6,190,350	B1	2/2001	Davis et al.
6,190,353	B1	2/2001	Makower et al.
6,200,258	B1	3/2001	Slater et al.
6,203,507	B1	3/2001	Wadsworth et al.
6,203,524	B1	3/2001	Burney et al.
6,203,568	B1	3/2001	Lombardi et al.
6,213,957	B1	4/2001	Milliman et al.
6,214,045	B1	4/2001	Corbitt, Jr. et al.
6,214,315	B1	4/2001	Greff et al.
6,220,248	B1	4/2001	Voegele et al.
6,224,630	B1	5/2001	Bao et al.
6,228,049	B1 *	5/2001	Schroeder A61B 10/0233 128/898
6,228,055	B1	5/2001	Foerster et al.
6,231,615	B1	5/2001	Preissman
6,234,177	B1 *	5/2001	Barsch A61B 90/39 128/897
6,241,687	B1	6/2001	Voegele et al.
6,241,734	B1	6/2001	Scribner et al.
6,251,135	B1	6/2001	Stinson et al.
6,251,418	B1	6/2001	Ahern et al.
6,261,243	B1	7/2001	Burney et al.
6,261,302	B1	7/2001	Voegele et al.
6,264,917	B1	7/2001	Klaveness et al.
6,270,464	B1	8/2001	Fulton, III et al.
6,270,472	B1	8/2001	Antaki et al.
6,287,278	B1	9/2001	Woehr et al.
6,287,332	B1	9/2001	Bolz et al.
6,289,229	B1	9/2001	Crowley
6,306,154	B1	10/2001	Hudson et al.
6,312,429	B1	11/2001	Burbank et al.
6,316,522	B1	11/2001	Loomis et al.
6,325,789	B1	12/2001	Janzen et al.
6,335,029	B1	1/2002	Kamath et al.
6,336,904	B1	1/2002	Nikolchev
6,340,367	B1	1/2002	Stinson et al.
6,343,227	B1	1/2002	Crowley
6,347,240	B1	2/2002	Foley et al.
6,347,241	B2	2/2002	Burbank et al.
6,350,244	B1	2/2002	Fisher
6,350,274	B1	2/2002	Li
6,354,989	B1	3/2002	Nudeshima
6,356,112	B1	3/2002	Tran et al.
6,356,782	B1	3/2002	Sirimanne et al.
6,358,217	B1	3/2002	Bourassa
6,363,940	B1	4/2002	Krag

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,371,904 B1 4/2002 Sirimanne et al.
6,394,965 B1 5/2002 Klein
6,403,758 B1 6/2002 Loomis
6,405,733 B1 6/2002 Fogarty et al.
6,409,742 B1 6/2002 Fulton, III et al.
6,419,621 B1 7/2002 Sioshansi et al.
6,424,857 B1 7/2002 Henrichs et al.
6,425,903 B1 7/2002 Voegele
6,427,081 B1 7/2002 Burbank et al.
6,436,030 B2 8/2002 Rehil
6,447,524 B1 9/2002 Knodel et al.
6,447,527 B1 9/2002 Thompson et al.
6,450,937 B1 9/2002 Mercereau et al.
6,450,938 B1 9/2002 Miller
6,471,700 B1 10/2002 Burbank et al.
6,478,790 B2 11/2002 Bardani
6,506,156 B1 1/2003 Jones et al.
6,511,468 B1 1/2003 Cragg et al.
6,511,650 B1 1/2003 Eiselt et al.
6,537,193 B1 3/2003 Lennox
6,540,981 B2 4/2003 Klaveness et al.
6,544,185 B2 4/2003 Montegrande
6,544,231 B1 4/2003 Palmer et al.
6,551,253 B2 4/2003 Worm et al.
6,554,760 B2 4/2003 Lamoureux et al.
6,562,317 B2 5/2003 Greff et al.
6,564,806 B1 5/2003 Fogarty et al.
6,565,551 B1 5/2003 Jones et al.
6,567,689 B2 5/2003 Burbank et al.
6,575,888 B2 6/2003 Zamora et al.
6,575,991 B1 * 6/2003 Chesbrough A61B 19/54 606/185
6,585,773 B1 7/2003 Xie
6,605,047 B2 8/2003 Zarins et al.
6,610,026 B2 8/2003 Cragg et al.
6,613,002 B1 9/2003 Clark et al.
6,616,630 B1 9/2003 Woehr et al.
6,626,850 B1 9/2003 Chau et al.
6,626,899 B2 9/2003 Houser et al.
6,628,982 B1 9/2003 Thomas et al.
6,629,947 B1 10/2003 Sahatjian et al.
6,636,758 B2 10/2003 Sanchez et al.
6,638,234 B2 10/2003 Burbank et al.
6,638,308 B2 10/2003 Corbitt, Jr. et al.
6,652,442 B2 11/2003 Gatto
6,656,192 B2 12/2003 Espositio et al.
6,659,933 B2 12/2003 Asano
6,662,041 B2 12/2003 Burbank et al.
6,699,205 B2 3/2004 Fulton, III et al.
6,712,774 B2 3/2004 Voegele et al.
6,712,836 B1 3/2004 Berg et al.
6,716,444 B1 4/2004 Castro et al.
6,725,083 B1 4/2004 Burbank et al.
6,730,042 B2 5/2004 Fulton et al.
6,730,044 B2 5/2004 Stephens et al.
6,746,661 B2 6/2004 Kaplan
6,746,773 B2 6/2004 Llanos et al.
6,752,154 B2 6/2004 Fogarty et al.
6,766,186 B1 7/2004 Hoyns et al.
6,774,278 B1 8/2004 Ragheb et al.
6,780,179 B2 8/2004 Lee et al.
6,824,507 B2 11/2004 Miller
6,824,527 B2 11/2004 Gollobin
6,846,320 B2 1/2005 Ashby et al.
6,862,470 B2 3/2005 Burbank et al.
6,863,685 B2 3/2005 Davila et al.
6,881,226 B2 4/2005 Corbitt, Jr. et al.
6,889,833 B2 5/2005 Seiler et al.
6,899,731 B2 5/2005 Li et al.
6,918,927 B2 7/2005 Bates et al.
6,936,014 B2 8/2005 Vetter et al.
6,939,318 B2 9/2005 Stenzel
6,945,973 B2 9/2005 Bray
6,951,564 B2 10/2005 Espositio et al.
6,958,044 B2 10/2005 Burbank et al.
6,992,233 B2 1/2006 Drake et al.
6,993,375 B2 1/2006 Burbank et al.
6,994,712 B1 2/2006 Fisher et al.
6,996,433 B2 2/2006 Burbank et al.
7,001,341 B2 2/2006 Gellman et al.
7,008,382 B2 3/2006 Adams et al.
7,014,610 B2 3/2006 Koulik
7,025,765 B2 4/2006 Balbierz et al.
7,044,957 B2 5/2006 Foerster et al.
7,047,063 B2 5/2006 Burbank et al.
7,083,576 B2 8/2006 Zarins et al.
7,125,397 B2 10/2006 Woehr et al.
7,135,978 B2 11/2006 Gisselberg et al.
7,160,258 B2 1/2007 Imran et al.
7,172,549 B2 2/2007 Slater et al.
7,189,206 B2 3/2007 Quick et al.
7,214,211 B2 5/2007 Woehr et al.
7,229,417 B2 6/2007 Foerster et al.
7,236,816 B2 6/2007 Kumar et al.
7,264,613 B2 9/2007 Woehr et al.
7,280,865 B2 10/2007 Adler
7,294,118 B2 11/2007 Saulenas et al.
7,297,725 B2 11/2007 Winterton et al.
7,329,402 B2 2/2008 Unger et al.
7,329,414 B2 2/2008 Fisher et al.
7,407,054 B2 8/2008 Seiler et al.
7,416,533 B2 8/2008 Gellman et al.
7,424,320 B2 9/2008 Chesbrough et al.
7,449,000 B2 11/2008 Adams et al.
7,527,610 B2 5/2009 Erickson
7,534,452 B2 5/2009 Chernomorsky et al.
7,535,363 B2 5/2009 Gisselberg et al.
7,565,191 B2 7/2009 Burbank et al.
7,569,065 B2 8/2009 Chesbrough et al.
7,577,473 B2 8/2009 Davis et al.
7,637,948 B2 12/2009 Corbitt, Jr.
7,651,505 B2 1/2010 Lubock et al.
7,668,582 B2 2/2010 Sirimanne et al.
7,670,350 B2 3/2010 Selis
7,783,336 B2 8/2010 Macfarlane et al.
7,792,569 B2 9/2010 Burbank et al.
7,819,819 B2 10/2010 Quick et al.
7,819,820 B2 10/2010 Field et al.
7,844,319 B2 11/2010 Susil et al.
7,871,438 B2 1/2011 Corbitt, Jr.
7,877,133 B2 1/2011 Burbank et al.
7,914,553 B2 3/2011 Ferree
7,945,307 B2 5/2011 Lubock et al.
7,983,734 B2 7/2011 Jones et al.
8,011,508 B2 9/2011 Seiler et al.
8,027,712 B2 9/2011 Sioshansi et al.
8,052,658 B2 11/2011 Field
8,052,708 B2 11/2011 Chesbrough et al.
8,064,987 B2 11/2011 Carr, Jr.
8,128,641 B2 3/2012 Wardle
8,157,862 B2 4/2012 Corbitt, Jr.
8,177,792 B2 5/2012 Lubock et al.
8,306,602 B2 11/2012 Sirimanne et al.
8,320,993 B2 11/2012 Sirimanne et al.
8,320,994 B2 11/2012 Sirimanne et al.
8,361,082 B2 1/2013 Jones et al.
8,401,622 B2 3/2013 Talpade et al.
8,579,931 B2 11/2013 Chesbrough et al.
8,626,269 B2 1/2014 Jones et al.
8,626,270 B2 1/2014 Burbank et al.
8,639,315 B2 1/2014 Burbank et al.
8,668,737 B2 3/2014 Corbitt, Jr.
8,680,498 B2 3/2014 Corbitt et al.
8,718,745 B2 5/2014 Burbank et al.
8,784,433 B2 7/2014 Lubock et al.
8,965,486 B2 2/2015 Burbank et al.
9,044,162 B2 6/2015 Jones et al.
9,149,341 B2 10/2015 Jones et al.
9,237,937 B2 1/2016 Burbank et al.
2001/0006616 A1 7/2001 Leavitt et al.
2002/0004060 A1 1/2002 Heublein et al.
2002/0016625 A1 2/2002 Falotico et al.
2002/0022883 A1 2/2002 Burg
2002/0026201 A1 2/2002 Foerster et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2002/0044969 A1 4/2002 Harden et al.
2002/0045842 A1 4/2002 Van Bladel et al.
2002/0052572 A1 5/2002 Franco et al.
2002/0055731 A1 5/2002 Atala et al.
2002/0058868 A1 5/2002 Hoshino et al.
2002/0058882 A1 5/2002 Fulton, III et al.
2002/0077687 A1 6/2002 Ahn
2002/0082517 A1 6/2002 Klein
2002/0082519 A1 6/2002 Miller et al.
2002/0082682 A1 6/2002 Barclay et al.
2002/0082683 A1 6/2002 Stinson et al.
2002/0095204 A1 7/2002 Thompson et al.
2002/0095205 A1 7/2002 Edwin et al.
2002/0107437 A1 8/2002 Sirimanne et al.
2002/0133148 A1 9/2002 Daniel et al.
2002/0143359 A1 10/2002 Fulton, III et al.
2002/0165608 A1 11/2002 Llanos et al.
2002/0177776 A1 11/2002 Crawford Kellar et al.
2002/0188195 A1 12/2002 Mills
2002/0193815 A1 12/2002 Foerster et al.
2002/0193867 A1 12/2002 Gladdish, Jr. et al.
2003/0032969 A1 2/2003 Gannoe et al.
2003/0036803 A1 2/2003 McGhan
2003/0051735 A1 3/2003 Pavcnik et al.
2003/0116806 A1 6/2003 Kato
2003/0165478 A1 9/2003 Sokoll
2003/0191355 A1 10/2003 Ferguson
2003/0199887 A1 10/2003 Ferrera et al.
2003/0225420 A1 12/2003 Wardle
2003/0236573 A1 12/2003 Evans et al.
2004/0001841 A1 1/2004 Nagavarapu et al.
2004/0002650 A1 1/2004 Mandrusov et al.
2004/0016195 A1 1/2004 Archuleta
2004/0024304 A1 2/2004 Foerster et al.
2004/0059341 A1 3/2004 Gellman et al.
2004/0068312 A1 4/2004 Sigg et al.
2004/0073284 A1 4/2004 Bates et al.
2004/0097981 A1 5/2004 Selis
2004/0101479 A1 5/2004 Burbank et al.
2004/0101548 A1 5/2004 Pendharkar
2004/0106891 A1 6/2004 Langan et al.
2004/0116802 A1 6/2004 Jessop et al.
2004/0127765 A1 7/2004 Seiler et al.
2004/0133124 A1 7/2004 Bates et al.
2004/0153074 A1 8/2004 Bojarski et al.
2004/0162574 A1 8/2004 Viola
2004/0167619 A1 8/2004 Case et al.
2004/0204660 A1 10/2004 Fulton et al.
2004/0210208 A1 10/2004 Paul et al.
2004/0213756 A1 10/2004 Michal et al.
2004/0236212 A1* 11/2004 Jones A61B 17/0057 600/431
2004/0236213 A1 11/2004 Jones et al.
2004/0253185 A1 12/2004 Herweck et al.
2004/0265371 A1 12/2004 Looney et al.
2005/0019262 A1 1/2005 Chernomorsky et al.
2005/0020916 A1 1/2005 MacFarlane et al.
2005/0033157 A1 2/2005 Klien et al.
2005/0033195 A1 2/2005 Fulton et al.
2005/0036946 A1 2/2005 Pathak et al.
2005/0045192 A1 3/2005 Fulton et al.
2005/0059887 A1 3/2005 Mostafavi et al.
2005/0059888 A1 3/2005 Sirimanne et al.
2005/0065354 A1 3/2005 Roberts
2005/0065453 A1 3/2005 Shabaz et al.
2005/0080337 A1 4/2005 Sirimanne et al.
2005/0080339 A1 4/2005 Sirimanne et al.
2005/0100580 A1 5/2005 Osborne et al.
2005/0112151 A1 5/2005 Horng
2005/0113659 A1 5/2005 Pothier et al.
2005/0119562 A1 6/2005 Jones et al.
2005/0142161 A1 6/2005 Freeman et al.
2005/0143650 A1 6/2005 Winkel
2005/0165305 A1 7/2005 Foerster et al.
2005/0175657 A1 8/2005 Hunter et al.
2005/0181007 A1 8/2005 Hunter et al.
2005/0208122 A1 9/2005 Allen et al.
2005/0234336 A1 10/2005 Beckman et al.
2005/0268922 A1 12/2005 Conrad et al.
2005/0273002 A1 12/2005 Goosen et al.
2005/0277871 A1 12/2005 Selis
2006/0004440 A1 1/2006 Stinson
2006/0009800 A1 1/2006 Christianson et al.
2006/0025677 A1 2/2006 Verard et al.
2006/0025795 A1 2/2006 Chesbrough et al.
2006/0036158 A1 2/2006 Field et al.
2006/0036159 A1 2/2006 Sirimanne et al.
2006/0074443 A1 4/2006 Foerster et al.
2006/0079770 A1 4/2006 Sirimanne et al.
2006/0079805 A1 4/2006 Miller et al.
2006/0079829 A1 4/2006 Fulton et al.
2006/0079888 A1 4/2006 Mulier et al.
2006/0122503 A1 6/2006 Burbank et al.
2006/0155190 A1 7/2006 Burbank et al.
2006/0173280 A1 8/2006 Goosen et al.
2006/0173296 A1 8/2006 Miller et al.
2006/0177379 A1 8/2006 Asgari
2006/0217635 A1 9/2006 McCombs et al.
2006/0235298 A1 10/2006 Kotmel et al.
2006/0241385 A1 10/2006 Dietz
2006/0241411 A1 10/2006 Field et al.
2006/0292690 A1 12/2006 Liu et al.
2007/0021642 A1 1/2007 Lamoureux et al.
2007/0038145 A1 2/2007 Field
2007/0083132 A1 4/2007 Sharrow
2007/0106152 A1 5/2007 Kantrowitz et al.
2007/0135711 A1 6/2007 Chernomorsky et al.
2007/0142725 A1 6/2007 Hardin et al.
2007/0167736 A1 7/2007 Dietz et al.
2007/0167749 A1 7/2007 Yarnall et al.
2007/0239118 A1 10/2007 Ono et al.
2007/0287933 A1 12/2007 Phan et al.
2008/0039819 A1 2/2008 Jones et al.
2008/0091120 A1 4/2008 Fisher
2008/0097199 A1 4/2008 Mullen
2008/0188768 A1 8/2008 Zarins et al.
2008/0269638 A1 10/2008 Cooke et al.
2008/0294039 A1 11/2008 Jones et al.
2009/0000629 A1 1/2009 Hornscheidt et al.
2009/0024225 A1 1/2009 Stubbs
2009/0030309 A1 1/2009 Jones et al.
2009/0069713 A1 3/2009 Adams et al.
2009/0076484 A1 3/2009 Fukaya
2009/0131825 A1 5/2009 Burbank et al.
2009/0171198 A1 7/2009 Jones et al.
2009/0216118 A1 8/2009 Jones et al.
2009/0287078 A1 11/2009 Burbank et al.
2010/0010342 A1 1/2010 Burbank et al.
2010/0030072 A1 2/2010 Casanova et al.
2010/0082102 A1 4/2010 Govil et al.
2010/0198059 A1 8/2010 Burbank et al.
2010/0204570 A1 8/2010 Lubock
2010/0298696 A1 11/2010 Field et al.
2010/0324416 A1 12/2010 Burbank et al.
2011/0092815 A1 4/2011 Burbank et al.
2011/0184280 A1 7/2011 Jones et al.
2012/0078092 A1 3/2012 Jones et al.
2012/0179251 A1 7/2012 Corbitt, Jr.
2013/0144157 A1 6/2013 Jones et al.
2013/0281847 A1 10/2013 Jones et al.
2013/0310686 A1 11/2013 Jones et al.
2014/0058258 A1 2/2014 Chesbrough et al.
2014/0114186 A1 4/2014 Burbank et al.
2014/0142696 A1 5/2014 Corbitt, Jr.
2014/0243675 A1 8/2014 Burbank et al.
2015/0051477 A1 2/2015 Jones et al.
2016/0120510 A1 5/2016 Burbank et al.
2016/0128797 A1 5/2016 Burbank et al.
2016/0199150 A1 7/2016 Field et al.

FOREIGN PATENT DOCUMENTS

EP 0255123 A2 2/1988
EP 0292936 A2 11/1988

(56) **References Cited**

FOREIGN PATENT DOCUMENTS

EP	0458745	A1	11/1991
EP	0475077	A2	3/1992
EP	0552924	A1	7/1993
EP	0769281	A2	4/1997
EP	1114618	A2	7/2001
EP	1163888	A1	12/2001
EP	1281416	A2	6/2002
EP	1364628	A1	11/2003
EP	1493451	A1	1/2005
EP	1767167	A2	3/2007
FR	2646674	A3	11/1990
FR	2853521	A1	10/2004
GB	708148		4/1954
JP	2131757	A	5/1990
JP	2006516468	A	7/2006
WO	8906978	A1	8/1989
WO	9112823	A1	9/1991
WO	9314712	A1	8/1993
WO	9317671	A1	9/1993
WO	9317718	A1	9/1993
WO	9416647	A1	8/1994
WO	9507057	A1	3/1995
WO	9806346	A1	2/1998
WO	9908607	A1	2/1999
WO	9935966	A1	7/1999
WO	951143	A1	10/1999
WO	0023124	A1	4/2000
WO	0024332	A1	5/2000
WO	0028554	A1	5/2000
WO	0054689	A1	9/2000
WO	0108578	A1	2/2001
WO	0170114	A1	9/2001
WO	0207786	A2	1/2002
WO	0241786	A2	5/2002
WO	03000308	A1	1/2003
WO	2004045444	A2	6/2004
WO	2005013832	A1	2/2005
WO	2005089664	A1	9/2005
WO	2006056739	A2	6/2006
WO	2006097331		9/2006
WO	2006105353	A2	10/2006
WO	2007069105	A2	6/2007
WO	2008077081	A2	6/2008

OTHER PUBLICATIONS

Johnson & Johnson: Breast Biopsy (minimally invasive): Surgical Technique: Steps in the MAMOTOME Surgical Procedure. From http://www.jnjgateway.com. 3 pages.

Johnson & Johnson: New Minimally Invasive Breast Biopsy Device Receives Marketing Clearance in Canada; Aug. 6, 1999. From http://www.jnjgateway.com. 4 pages.

Johnson & Johnson: MAMMOTOME Hand Held Receives FDA Marketing Clearance for Minimally Invasive Breast Biopises; Sep. 1, 1999. From From http://www.jnjgateway.com. 5 pages.

Johnson & Johnson: The Mammotome Breast Biopsy System. From: http://www.breastcareinfo.com/aboutm.htm. 6 pages.

Cook Incorporated: Emoblization and Occlusion. From: www.cookgroup.com 6 pages.

Liberman, Laura, et al. Percutaneous Removal of Malignant Mammographic Lesions at Stereotactic Vacuum-assisted Biopsy. From: The Departments of Radiology, Pathology, and Surgery. Memorial Sloan-Kettering Cancer Center. From the 1997 RSNA scientific assembly. vol. 206, No. 3. pp. 711-715.

Shiga, et al., Preparation of Poly(D, L-lactide) and Copoly(lactide-glycolide) Microspheres of Uniform Size, J. Pharm. Pharmacol. 1996 48:891-895.

Eiselt, P. et al, "Development of Technologies Aiding Large—Tissue Engineering", Biotechnol. Prog., vol. 14, No. 1, pp. 134-140, 1998.

Armstong, J.S., et al., "Differential marking of Excision Planes in Screened Breast lesions by Organically Coloured Gelatins", Journal of Clinical Pathology, Jul. 1990, No. 43 (7) pp. 604-607, XP000971447 abstract; tables 1,2.

Fucci, V., et al., "Large Bowel Transit Times Using Radioopaque Markers in Normal Cats", J. of Am. Animal Hospital Assn., Nov.-Dec. 1995 31 (6) 473-477.

Schindlbeck, N.E, et al., "Measurement of Colon Transit Time", J. of Gastroenterology, No. 28, pp. 399-404, 1990.

Crook, et al. (Prostate Motion During Standard Radiotherapy As Assessed by Fiducial Markers, 1995, Radiotherapy and Oncology 37:35-42).

Zmora, et al. (Tailoring the pore architecture in 3-D alginate scaffolds by controlling the freezing regime during fabrication, 2001, Elsevier Science Ltd.).

Madihally, et al. (Porous chitosan scaffolds for tissue engineering, 1998, Elsevier Science Ltd.).

Fajardo, Laurie, et al., "Placement of Endovascular Embolization Microcoils to Localize the Site of Breast Lesions Removed at Stereotactic Core Biopsy", Radiology, Jan. 1998, pp. 275-278, vol. 206—No. 1.

H. J. Gent, M.D., et al., Stereotaxic Needle Localization and Cytological Diagnosis of Occult Breast Lesions, Annals of Surgery, Nov. 1986, pp. 580-584, vol. 204—No. 5.

Meuris, Bart, "Calcification of Aortic Wall Tissue in Prosthetic Heart Valves: Initiation, Influencing Factors and Strategies Towards Prevention", Thesis, 2007, pp. 21-36, Leuven University Press; Leuven, Belgium.

Shah, et al. (Polyethylene Glycol as a Binder for Tablets, vol. 66, No. 11, Nov. 1977, Journal of Pharmaceutical Sciences).

* cited by examiner

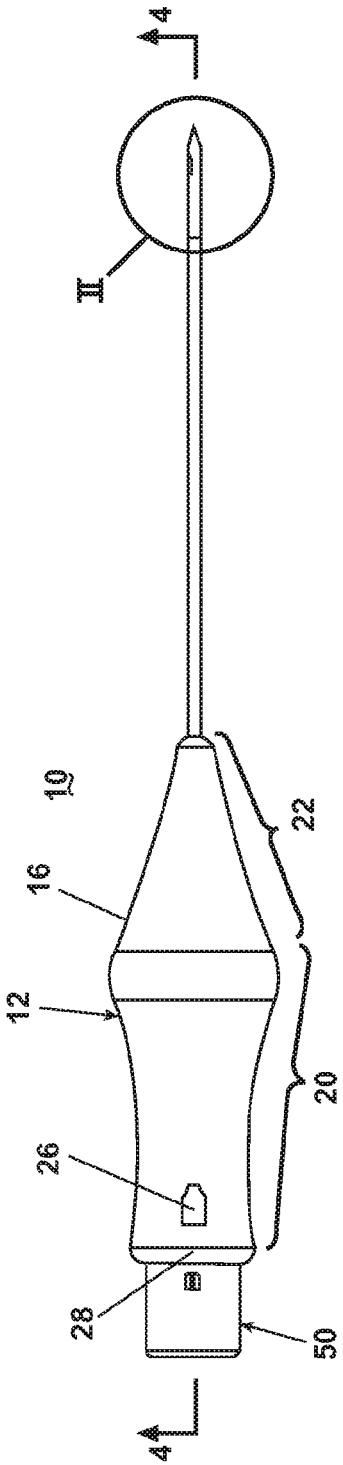


Fig. 1

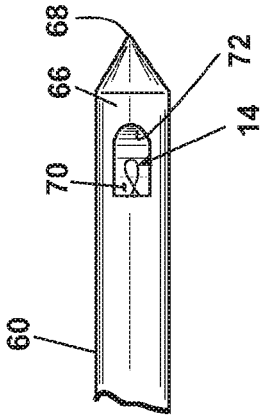


Fig. 3

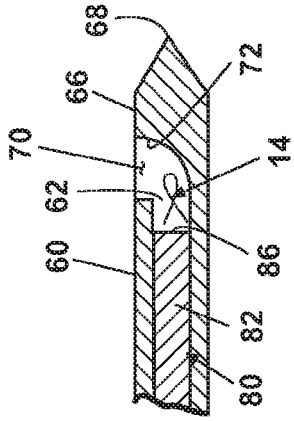


Fig. 2

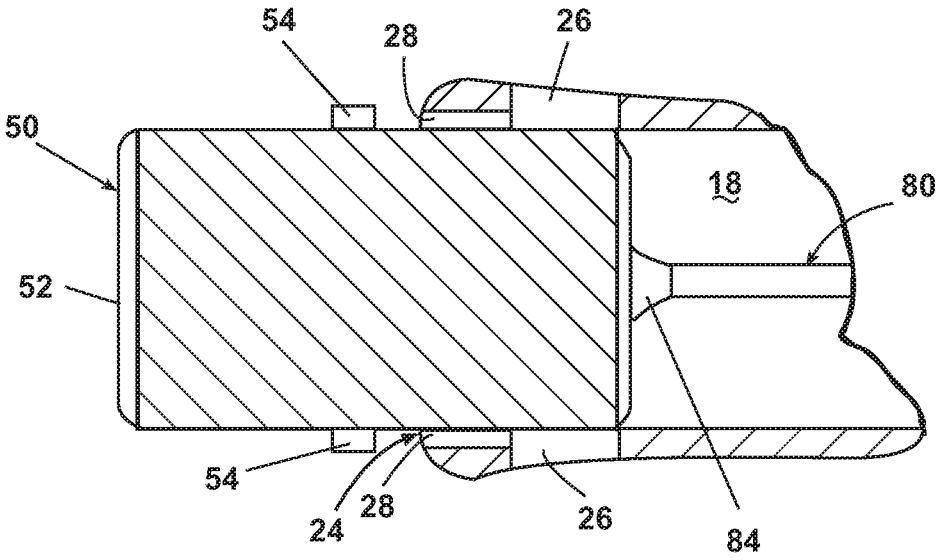


Fig. 4

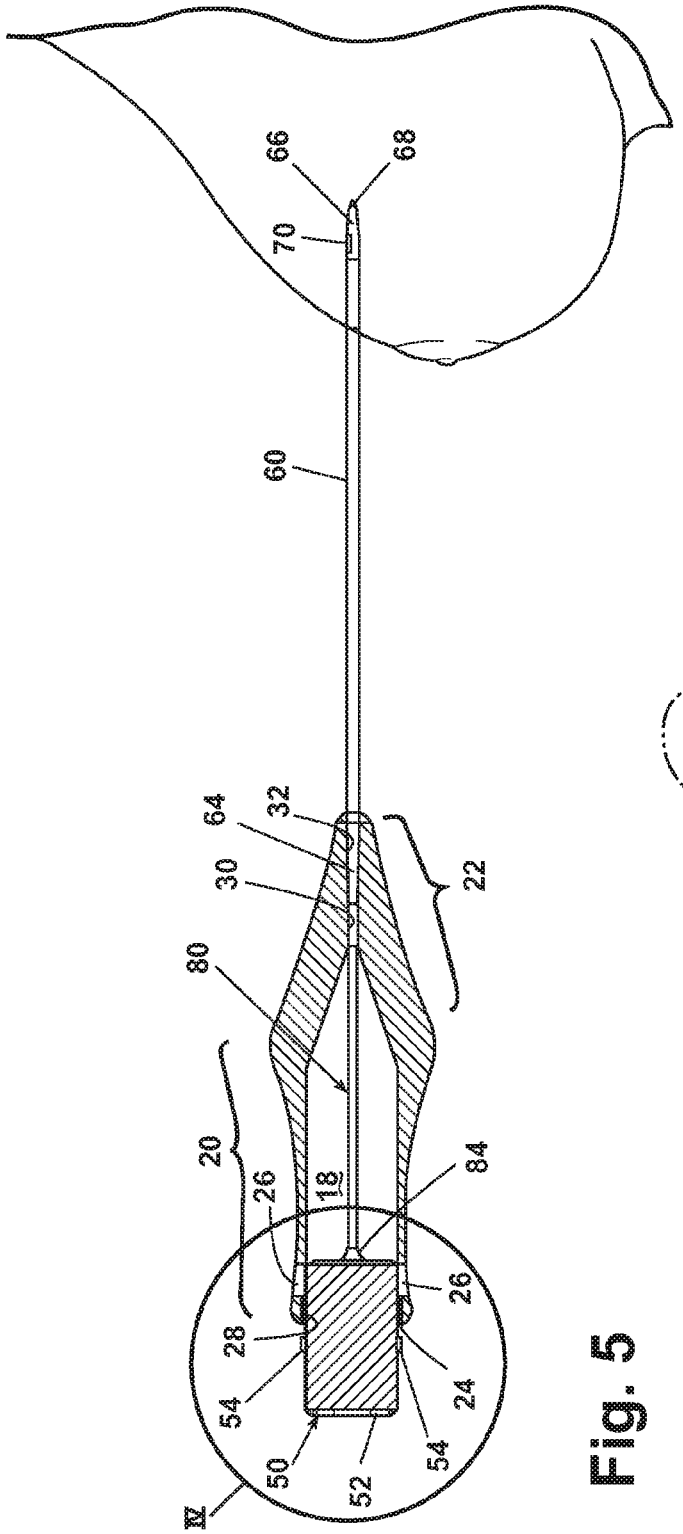

66
68
70
60
64
32
30
22
80
20
26
18
84
26
28
54
24
50
52
54
IV

Fig. 5

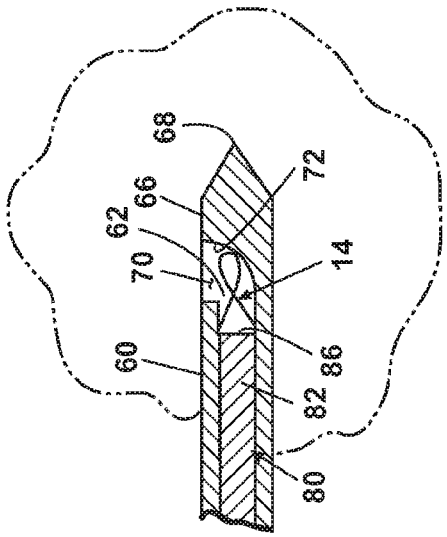

68
72
66
62
70
14
60
86
82
80

Fig. 6

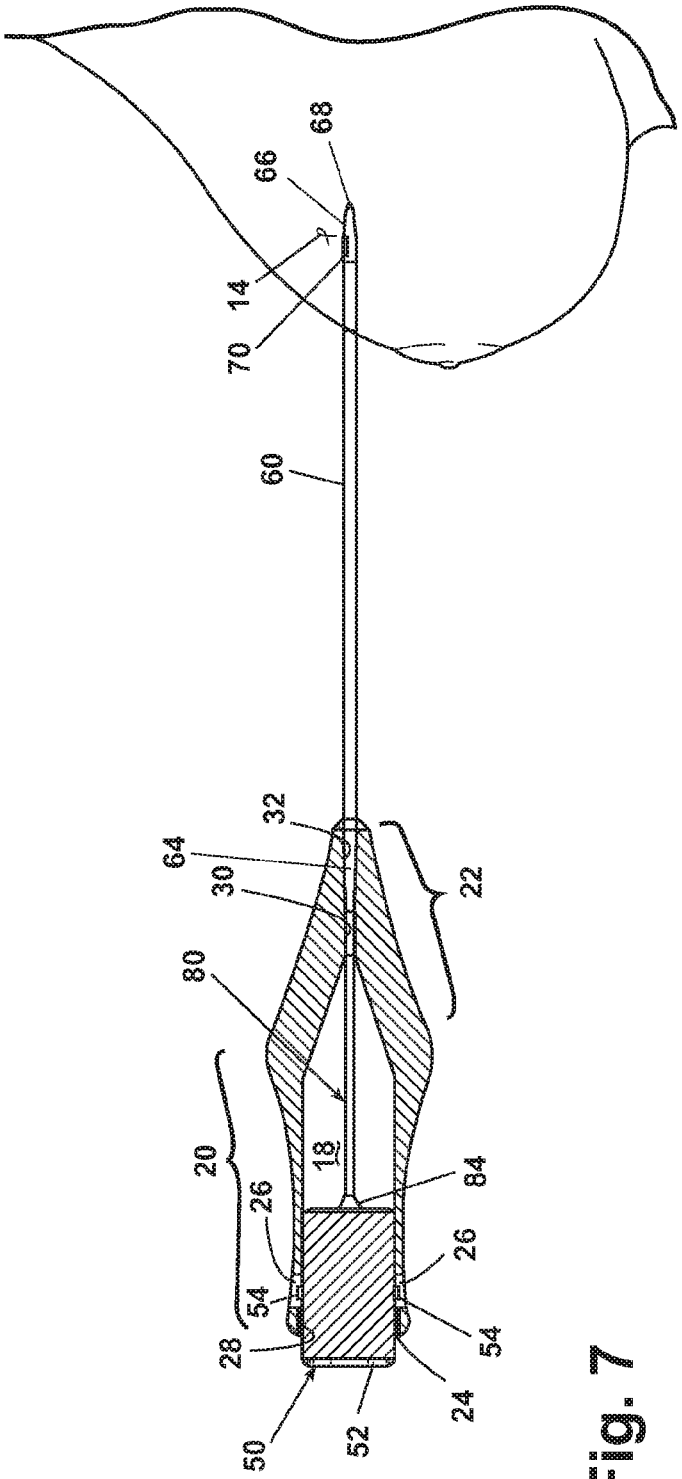

68
66
14
70
60
32
64
30
22
80
20
18
26
84
26
54
54
28
24
50
52

Fig. 7

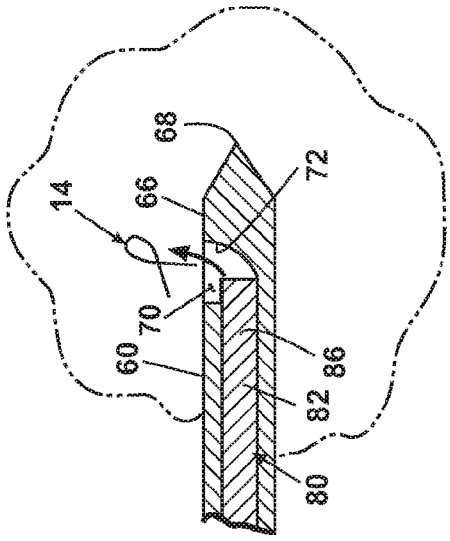

68
72
14
66
70
60
86
82
80

Fig. 8

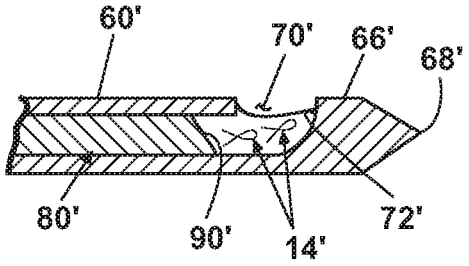


Fig. 9

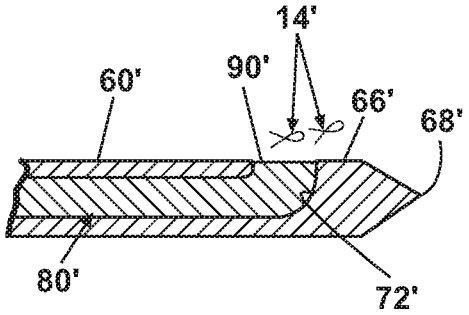


Fig. 10

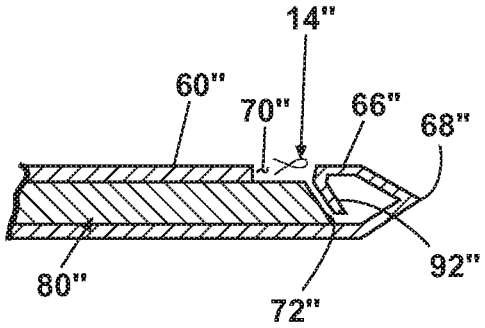


Fig. 11

SELF-CONTAINED, SELF-PIERCING, SIDE-EXPELLING MARKING APPARATUS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a divisional of U.S. application Ser. No. 15/078,847, filed Mar. 23, 2016, which is a continuation of U.S. application Ser. No. 12/850,844 filed Aug. 5, 2010, now abandoned, which is a continuation of U.S. application Ser. No. 11/275,918 filed Feb. 3, 2006, now U.S. Pat. No. 7,819,820, which is a continuation of U.S. application Ser. No. 10/710,587 filed Jul. 22, 2004, now abandoned, and is a continuation-in-part of U.S. application Ser. No. 10/707,044 filed Nov. 17, 2003, now U.S. Pat. No. 7,424,320, issued Sep. 9, 2008, which claims the benefit of U.S. provisional application Ser. No. 60/427,048 filed Nov. 18, 2002, all of which are incorporated herein by reference in their entirety.

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates generally to an apparatus for the percutaneous positioning of an imaging marker for identifying the location of a lesion in a biopsy procedure. More particularly, the invention relates to a self-contained marking apparatus that expels the imaging marker through the side of the marking device.

Description of the Related Art

Tissue biopsies are commonly performed on many areas and organs of the body where it is desirable to ascertain whether or not the biopsied tissue is cancerous. Often, a lesion or other tissue to be biopsied is identified through use of an imaging technique such as a computerized axial tomography (CAT) scan, ultrasonography, magnetic resonance imaging, and mammography.

One problem commonly encountered, especially in breast biopsies, is that the lesion is so small that the biopsy reduces its size to the extent that it is no longer visible by the imaging method employed. In such circumstances, it is desirable to place an imaging marker at the site of the biopsy to enable the medical practitioner subsequently to locate the lesion quickly and accurately in the event complete removal of the affected tissue is indicated. This problem is currently met by placing an imaging marker at the biopsy area by means of a cannula or similar device housing the marker.

There are currently two primary types of marking devices. One of the primary types is referred to as vacuum assisted biopsy devices (VAB's). The VAB devices are many times integrated with a mammography imaging system. They include a large diameter cannula, approximately 9 to 12 gage, or probe that is inserted into the breast tissue. Instruments, such as a biopsy device and a marking device, are introduced into the breast tissue through the large diameter cannula to take biopsy samples or mark a biopsy location.

The other primary type is self-contained marking devices comprising a small diameter, approximately 14 to 17 gage, open-end cannula and a stylet slidably received within the cannula. A marker is located in the cannula and expelled out the open-end upon the advancing of the stylet relative to the cannula.

One disadvantage of the VAB system is the biopsy and marking tools are integrated with the mammography imaging system. The capital investment of this type of system is substantial. Also, the biopsy and marking tools are typically designed to work only with the large diameter probe, which tends to lock the hospital or medical professional into the same source for the imaging system and the biopsy and marking tools. The VAB systems are also intended for the same components to be reused, which requires sterilization after each step. The various components are also typically flexible to help insert them through the probe. The VAB systems also have a relatively large diameter probe, which, all things being equal, the larger the diameter, the greater trauma to the surrounding tissue and the greater the pain or discomfort for the patient.

The self-contained marking devices address these disadvantages of the VAB systems. Since the self-contained marking device is not integrally incorporated with a particular imaging system, the self-contained marking devices can be used with any suitable imaging system and are not limited to just mammography. This permits the hospital or medical professional to mix and match the available imaging systems and self-contained marking devices to obtain the desired performance and cost-effectiveness.

The self-contained marking devices are typically disposable, which negates the need to sterilize them after each use. They also have a much smaller diameter, resulting in much less trauma to the surrounding tissue and pain to the patient.

A disadvantage of the self-contained systems is that the cannula has an open tip through which the marker is expelled. The open tip is generally closed by the marker residing in the cannula. However, the marker does not completely close off the open tip and it is possible for tissue to enter the open end of the cannula during the positioning of the marking device. The presence of tissue inside the open end of the cannula can interfere or make more difficult the expelling of the marker from the cannula.

The possibility for tissue being present in the open end of the cannula is, to some extent, related to the distance that the cannula is inserted through the tissue to the marking site. Thus, the manner in which the marking device is located at the biopsy site can impact the presence of tissue in the open end of the cannula. For example, the self-contained systems are sometimes used in combination with a positioning cannula that is inserted into the tissue mass with a stylet closing the end of the positioning cannula. In such a configuration, the stylet is removed once the positioning cannula is properly located relative to the biopsy site. Both the biopsy device and the marking device can be inserted and withdrawn through the positioning cannula. The use of the positioning cannula reduces the distance that the open end of the marking device cannula must travel through the tissue.

Alternatively, the marking device can be inserted without the positioning cannula. This is most common when it is desirable to place a marker without taking a biopsy. Under such circumstances, it is more likely that tissue will be received within the open end of the cannula. Therefore, it is more likely that the tissue will interfere with the expelling of the marker.

Therefore, it is desirable to have a self-contained marking device that can be used with or without a positioning cannula and which does not receive tissue within the open end of the cannula that might interfere with the expelling of the marker.

SUMMARY OF THE INVENTION

The invention relates to a marking apparatus for the percutaneous placement of an imaging marker at a predetermined location in a tissue mass to facilitate subsequent determination of the predetermined location. The marking apparatus comprises a handle, cannula, and plunger. The handle is to be grasped by a user to aid in the placement of the marker.

The cannula comprises a peripheral wall forming a lumen, with a proximal end carried by the handle, and a distal end terminating in a self-piercing tip. A lateral opening is formed in the peripheral wall and is open to the lumen.

A plunger having a distal end is slidably received within the lumen for movement between a ready position, where the distal end is spaced inwardly from the self-piercing tip to form a marker recess in communication with the lateral opening and sized to receive an imaging marker, and an expelled position, where the distal end is advanced a sufficient distance into the marker recess to expel a marker contained therein through the lateral opening.

One or more imaging markers can be positioned within the marker recess.

The handle, cannula, plunger are operably coupled such that they form a self-contained marking apparatus that can be easily and conveniently handled by a user to effect operation of the marking apparatus from the ready position to an expelled position.

The cannula is preferably sufficiently rigid and a distal end of the cannula is pointed to form the self-piercing tip. The cannula is 13 gage or less.

A ramp can be provided on at least one of the plunger and cannula to aid in expelling an imaging marker. The ramp can be located in the lumen adjacent the lateral opening. The distal end of the plunger can be flexible to be deflected toward the lateral opening by the ramp when the plunger is moved to the expelled position. The ramp can also be located on the distal end of the plunger.

The invention, in one form thereof, is directed to a marking apparatus for the percutaneous placement of an imaging marker in a tissue mass. The marking apparatus includes a handle to be grasped by a user, a rigid cannula and a stylet. The rigid cannula has a peripheral wall forming a lumen that carries the imaging marker, a proximal end coupled to the handle, a lateral opening in the peripheral wall that is open to the lumen, and a closed-off distal portion having a ramp adjacent the lumen. The closed-off distal portion extends distally from the ramp to terminate at a tissue piercing pointed tip. The ramp of the rigid cannula is curved to transition from the peripheral wall of the rigid cannula to the lateral opening of the rigid cannula. A stylet has a distal end, with at least the distal end of the stylet being flexible. The stylet is slidably received within the lumen of the rigid cannula for movement in the lumen. The ramp of the rigid cannula is adapted to engage the distal end of the stylet as the stylet is advanced through the lumen of the rigid cannula to guide the distal end of the stylet to a position to substantially close off the lateral opening of the rigid cannula having the tissue piercing tip.

The invention, in another form thereof, is directed to a marking apparatus for the percutaneous placement of an imaging marker in a tissue mass. The marking apparatus includes a handle to be grasped by a user, a cannula, and a stylet. The cannula has a peripheral wall forming a lumen that carries the imaging marker, a proximal end coupled to the handle, a lateral opening in the peripheral wall that is open to the lumen, and a closed-off distal portion having a ramp adjacent the lumen. The closed-off distal portion extends distally from the ramp to terminate at a tissue piercing pointed tip. The stylet has a distal end with an angled surface. The stylet is disposed in the lumen and movable in the lumen between a ready position and an expelled position, such that when the stylet is advanced through the lumen to the expelled position the ramp deflects the distal end of the stylet toward the lateral opening such that at the expelled position the angled surface is flush with the peripheral wall of the cannula at the lateral opening of the cannula.

The invention, in another form thereof, is directed to a marking apparatus for the percutaneous placement of an imaging marker in a tissue mass. The marking apparatus includes a handle to be grasped by a user, a cannula, and a stylet. The cannula has a peripheral wall forming a lumen that carries the imaging marker, a proximal end carried by the handle, a closed-off distal portion terminating in a self-piercing tip, a ramp integrated with the closed-off distal portion, and a lateral opening in the peripheral wall. The lateral opening extends in a region between the proximal end and the closed-off distal portion of the cannula. The lateral opening has a proximal extent and a distal extent, the distal extent being closer to the self-piercing tip than the proximal extent. The stylet includes a distal end. The stylet is slidably received within the lumen for movement between a ready position, wherein the distal end of the stylet is spaced inwardly from the self-piercing tip to form a marker recess in communication with the lateral opening, and an expelled position, wherein the distal end of the stylet is advanced a sufficient distance into the marker recess to expel the imaging marker contained in the lumen through the lateral opening of the cannula. When the distal end of the stylet is at the expelled position the distal end of the stylet is deflected by the ramp to close off the lateral opening of the cannula between the proximal extent and the distal extent of the lateral opening.

The invention also relates to a method for percutaneously placing a marker at a predetermined location in a tissue mass using a self-piercing, side-ejecting, self-contained marking apparatus comprising a cannula defining a lumen and terminating in a self-piercing tip, with a lateral opening in communication with the lumen, and a plunger slidably received within the lumen for expelling a marker in the lumen through the lateral opening. The method comprises: inserting the cannula into the tissue mass by puncturing an exterior of the tissue mass with the self-piercing tip, and expelling the marker through the lateral opening by sliding the plunger within the lumen.

The inserting step can comprise locating the lateral opening near a predetermined location in the tissue mass where it is desired to be marked. Preferably, the lateral opening is located beneath the predetermined location.

The expelling step comprises expelling multiple markers into the tissue mass. At least one of the multiple markers can be expelled at a different location in the tissue mass than another of the multiple markers.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. **1** is a plan view of a self-contained, self-piercing, and side-expelling marking apparatus comprising an actuator, a cannula with a side opening, and a stylet for laterally expelling a marker through the side opening in accordance with the invention.

FIG. **2** is an enlarged sectional view of the area II of FIG. **1**, illustrating the relationship between the cannula, stylet and marker prior to the expelling of the marker.

FIG. **3** is an enlarged top view of the cannula tip of FIG. **2**.

FIG. **4** is an enlarged sectional view of a portion of the actuator.

FIG. **5** is a sectional view of the marking device inserted into a tissue mass such that the cannula side opening is

adjacent an area to be marked, with the stylet shown in a ready position and the marker still retained within the cannula lumen.

FIG. **6** is an enlarged sectional view of the cannula tip of FIG. **5**.

FIG. **7** is a sectional view of the marking device inserted into a tissue mass such that the cannula side opening is adjacent an area to be marked, with the stylet shown in a expelled position and the marker expelled through the side opening into the surrounding tissue mass.

FIG. **8** is an enlarged sectional view of the cannula tip of FIG. **7**.

FIG. **9** is a sectional view of an alternative design for the cannula and stylet according to the invention, with the stylet having a flexible tip and shown in the ready position.

FIG. **10** is a sectional view of the cannula and stylet of FIG. **9** with the stylet shown in the expelled position.

FIG. **11** is a sectional view of a second alternative design for the cannula and stylet according to the invention, with the stylet having a ramped tip and shown in the expelled position.

DETAILED DESCRIPTION

FIGS. **1-4** illustrate a self-contained, self-penetrating, side-expelling marking apparatus **10** according to the invention, which is capable of the percutaneous placement of a imaging marker at a desired location, such as at a tissue biopsy site or a lesion site in a breast. The marking apparatus **10** comprises an introducer **12** and an imaging marker **14** (FIG. **2**) contained within the introducer **12**. The introducer **12** includes an actuator **16** having a hollow interior **18**. The actuator **16** comprises a grip portion **20** from which extends a tapered nose portion **22**. The grip portion **20** defines a rear opening **24** that provides access to the hollow interior **18**. A pair of detents **26** are formed in the grip portion **20** near the rear opening **24**. Channels **28** are formed on the interior surface of the grip portion **20** and extend from the rear opening **24** to the detents **26**.

The nose portion **22** comprises a guide passage **30** extending from the tip of the nose portion **22** to the hollow interior **18** of the actuator **16**. The guide passage **30** decreases in diameter inwardly from the tip of the nose portion to form a cannula seat **32** (FIG. **5**).

A plunger **50** comprises a cylindrical body **52** from which extend a pair of catches **54** at diametrically opposed positions. The cylindrical body **52** is sized so that it is slidably received within the rear opening **24** of the actuator **16** where it is so oriented with respect to the actuator such that the catches **54** are aligned with the guide channels **28**. The plunger is free to reciprocate within the grip portion **20** of the actuator **16**.

A cannula **60** is mounted to the introducer **12**. The cannula **60** defines a hollow interior in the form of a lumen **62** and comprises a proximal end **64** and a distal end **66**. The proximal end **64** (FIG. **5**) is mounted within the cannula seat **32** to secure the cannula **60** to the introducer **12**. The distal end **66** terminates in a closed-off tip **68** to provide the marking apparatus with self-piercing functionality. The closed-off tip **68** is illustrated as being pointed, but other suitable shapes are possible.

The cannula **60** is preferably 13 gage or less in size. The cannula **60** is also preferably rigid. That is, the cannula does not substantially flex. The rigidity of the cannula aids in inserting the cannula into a tissue mass, without the aid of a guide needle or guide cannula.

A side opening **70** is formed in the cannula **60** and extends entirely through the cannula such that the lumen **62** is in communication with the exterior of the cannula **60** through the side opening **70**. The side opening is preferably located behind the closed-off tip **68**.

A ramp **72** is provided on the interior of the cannula **60**. The ramp **72** is illustrated as being integrally formed with the closed-off tip **68**. Such a configuration can result in a solid distal end **66** as illustrated. However, the distal end can be hollow and the ramp **72** can be formed by separately from the distal end **66**.

The ramp **72** extends diametrically across the lumen **62** and terminates at the side opening **70**. With this configuration, the ramp **72** aids in directing an imaging marker **14** stored in the lumen through the side opening **70** and beyond the exterior of the cannula.

A stylet **80** comprising a shaft **82** and a base **84** is received within the hollow interior **18** of the actuator **16** in a manner such that the shaft **82** extends through the guide passage **30** and into the cannula interior **62** and the stylet base **84** lies within the hollow interior **18** and is mounted to the plunger **50**. Thus, the reciprocation of the plunger **50** relative to the grip portion **20** results in a reciprocation of the stylet **80** within the cannula **60**.

The stylet **80** terminates in a distal end **86**, which, when the marking apparatus is in the ready position, is spaced from the distal end **66** of the cannula **60** to form a marker recess therebetween. As illustrated, a single marker **14** is stored within the marker recess. It is within the scope of the invention for multiple markers to be received within the marker recess.

As is shown, the foregoing construction provides a marking apparatus that is preassembled as a self-contained unit and prepackaged, all under sterile conditions, thereby affording the practitioner substantially greater convenience and reliability, while eliminating the need for sterilizing the self-contained unit after use. Preferably, the self-contained unit is disposed of after it is used.

Referring to FIGS. **5-8**, in operation, the introducer **12** begins in the ready condition shown in FIGS. **5** and **6**. In this condition, the distal end **86** of the stylet **80** is received within the cannula and spaced from the closed-off distal end **66** of the cannula to define a marker recess in which a marker **14** is stored. The plunger **50** is in a position relative to the grip portion **20** in which the catches are outside the grip portion; that is, they are not received within the detents **26**. However, the plunger **50** is so oriented with respect to the grip portion that the catches **54** are aligned with the guide channels **28**.

With the introducer in the ready condition, the cannula is positioned within the tissue mass such that the side opening **70** is at or near the location of a tissue mass where it is desired to place the marker. In the case of marking a biopsy site, the side opening is preferably placed adjacent the biopsy site.

To place the side opening adjacent the site to be marked, the medical professional grasps the grip portion **20** of the actuator and presses the closed-off tip **68** against the exterior of the tissue mass to puncture the tissue mass. The medical professional continues applying force to the grip portion **20** to drive the cannula **60** to the desired location within the tissue mass.

The closed tip **68** helps separate the tissue of the tissue mass to make it easier to insert the cannula within the tissue mass to the desired location. A starter incision can be made in the exterior of the tissue mass to reduce the initial force needed to start the insertion.

The used of a side opening **70** instead of a tip opening found in the prior art self-contained devices helps prevent the accumulation of tissue within the lumen **62** upon the insertion of the cannula **60** into the tissue mass. The closed tip **68** also helps in that it separates the tissue to form a path through which the side opening passes. Since the side opening is parallel to the path, there is much less tendency for the insertion of the cannula to force tissue into the side opening as could occur in the prior-art front opening cannulae.

Typically, a suitable imaging system will be used by the medical professional to help guide the cannula to the desired location within the tissue mass. Examples of contemporary imaging systems include: stereotactic, x-ray, ultrasound, CAT scan, or MRI. The invention is not limited to any particular type of imaging system.

Once the cannula is positioned at the desired location, the plunger **50** is moved from a first or ready condition as illustrated in FIGS. **5** and **6** to a second or expelled condition as illustrated in FIGS. **7** and **8**. As the plunger is moved, the stylet **80** is advanced into the marker recess to drive the marker **14** up the ramp **72**. The continued advancement of the stylet **80** ultimately drives the marker **14** through the side opening **70** and into the adjacent tissue.

Once the stylet is in the expelled position, the cannula can be withdrawn to leave the marker in the tissue. To withdraw the cannula, the medical professional pulls on the actuator to withdraw the cannula from the tissue mass. After use, the marking apparatus is disposed of, negating the need for sterilization.

As illustrated, the rigid cannula in combination with the closed-off tip **68** provides an ideal structure for inserting the device directly into the tissue without the need for a guide needle or cannula. This is advantageous in that it reduces the size of the opening formed in the tissue and thereby reducing the trauma to the patient. The closed-off tip is used to puncture the exterior of the tissue mass. While the marking apparatus of the invention can be used with a guide needle or cannula, there is no need to do so because of the self-piercing nature of the invention.

FIGS. **9** and **10** illustrate an alternative design for the stylet in the ready and expelled conditions, respectively. The alternative stylet **80'** is essentially identical to the stylet **80**, except that the distal end **66'** is made from a resilient material and has an angled surface **90'**. The resilient material permits the distal end **66'** to deflect when contacting the ramp **72'**, such that the distal end **66'** generally follows the shape of the ramp **72'**. The angle of the angled surface **90'** is preferably selected such that the angled surface substantially closes off the side opening **70'** when the stylet is in the expelled condition, which will ensure that the marker is completely expelled through the side opening **70'**. It will also ensure that no portion of the marker **14** will be pulled back into the side opening **70'** due to the vacuum forces created upon the withdrawal of the cannula. The angled surface **90'** functions like the ramp **72** in that it helps to deflect the marker **14** through the side opening.

FIG. **11** illustrates another alternative design for the stylet and cannula. In this alternative design, the distal end **66"** of the stylet **80"** includes a ramp **72"**. A resilient end wall **92"** is used instead of the ramp **72** of the cannula. The space between the ramp **72"** and the resilient end wall **92"** defines the marker recess in which multiple markers **14"** are stored. The advancement of the stylet from the ready condition to the expelled condition drives the markers up the ramp **72"**. When contacted by the ramp **72"**, the resilient end wall **92"** deflects to permit the ramp **72"** to slide beneath and into the distal end closed tip **68"** of the cannula.

In all of the embodiments, multiple markers can be located within the cannula and expelled at the same or different locations within the tissue mass.

While the invention has been specifically described in connection with certain specific embodiments thereof, it is to be understood that this is by way of illustration and not of limitation, and the scope of the appended claims should be construed as broadly as the prior art will permit.

We claim:

1. A marking apparatus for the percutaneous placement of an imaging marker in a tissue mass, the marking apparatus comprising:

a handle configured to be grasped by a user, the handle having a rear opening;

a rigid cannula having:

a proximal end coupled to the handle;

a peripheral wall forming a lumen that carries the imaging marker;

a lateral opening in the peripheral wall that is open to the lumen, the lateral opening having a proximal extent and a distal extent;

a closed-off distal portion distal to the lateral opening; and

a resilient end wall extending downwardly from the peripheral wall at the distal extent of the lateral opening;

a stylet having a proximal end and a distal end, the distal end of the stylet having a ramp, the stylet being slidably received within the lumen of the rigid cannula for movement in the lumen, the resilient end wall of the rigid cannula being configured to deflect upon engagement of the ramp such that the ramp of the distal end of the stylet passes beneath the resilient end wall and into the closed-off distal portion when the stylet is advanced through the lumen of the rigid cannula to an extended position to substantially close off the lateral opening of the rigid cannula; and

a plunger received in the rear opening of the handle, the plunger connected to the stylet and configured to move relative to the handle.

2. The marking apparatus of claim **1**, wherein only the distal end of the stylet and the resilient end wall close off the lateral opening when the stylet is in the extended position.

3. The marking apparatus of claim **1**, configured such that the stylet has a ready position wherein the distal end of the stylet is positioned in the lumen proximal to the extended position, in the ready position the stylet is spaced inwardly from the closed-off distal portion to form a marker recess that is in communication with the lateral opening and that is sized to receive the imaging marker, and configured such that when the stylet is moved to the extended position, the ramp engages and expels the imaging marker contained in the lumen of the rigid cannula through the lateral opening, and wherein the resilient end wall engages the ramp at the distal end of the stylet to substantially close off the lateral opening of the rigid cannula only after the imaging marker is expelled.

4. The marking apparatus of claim **3**, further comprising multiple imaging markers contained within the marker recess.

5. The marking apparatus of claim **1**, wherein the handle, the rigid cannula, the stylet, and the plunger are operably coupled to form a self-contained marking apparatus.

6. The marking apparatus of claim 1, wherein the handle has a detent, and the plunger has a catch configured to selectively engage the detent of the handle to latch the stylet in the extended position.

7. A marking apparatus for the percutaneous placement of an imaging marker in a tissue mass, comprising:

a handle configured to be grasped by a user, the handle having a rear opening;

a cannula having:

a peripheral wall forming a lumen that carries the imaging marker,

a proximal end coupled to the handle,

a lateral opening in the peripheral wall that is open to the lumen,

a closed-off distal portion having a distal void and a pointed tip, wherein the distal void is distal to the lateral opening and is proximal to the pointed tip, and

a resilient end wall proximal to the distal void;

a stylet having a distal end with an angled surface, the stylet being disposed in the lumen and movable in the lumen between a ready position and an expelled position, the stylet being configured to advance through the lumen to the expelled position, the resilient end wall being configured to deflect distally and beneath the resilient end wall and into the distal void as the stylet advances through the lumen into the expelled position, the angled surface of the stylet being configured to drive the imaging marker out of the lumen through the lateral opening of the cannula as the stylet advances into the expelled position; and

a plunger received in the rear opening of the handle and configured to move relative to the handle, the plunger being connected to the stylet.

8. The marking apparatus of claim 7, wherein the resilient end wall cantilevers from the peripheral wall of the cannula to separate the distal void from the lateral opening.

9. The marking apparatus of claim 7, wherein the stylet closes off the lateral opening when the stylet is in the expelled position.

10. The marking apparatus of claim 7, wherein the handle has a detent, and the plunger has a catch configured to selectively engage the detent of the handle to latch the stylet in the extended position.

11. A marking apparatus for the percutaneous placement of an imaging marker in a tissue mass, the marking apparatus comprising:

a handle having a rear opening;

a cannula having:

a peripheral wall forming a lumen that carries the imaging marker,

a proximal end carried by the handle,

a closed-off distal portion terminating in a self-piercing tip,

a lateral opening in the peripheral wall, wherein the lateral opening extends in a region between the proximal end of the cannula and the closed-off distal portion of the cannula, the lateral opening having a proximal extent and a distal extent, and

a cantilever end wall extending into the lumen from the peripheral wall at the distal extent of the lateral opening, the cantilever end wall having a distal free end that is suspended in the lumen above the peripheral wall;

a stylet having a proximal end and a distal end, the stylet being slidably received within the lumen for movement between a ready position, wherein the distal end of the stylet is spaced inwardly from the self-piercing tip to form a marker recess in communication with the lateral opening, and an expelled position, wherein the distal end of the stylet is advanced a sufficient distance into the marker recess to expel the imaging marker contained in the lumen through the lateral opening of the cannula, the cantilever end wall of the cannula being configured to deflect upon engagement of the distal end of the stylet such that the distal end of the stylet passes beneath the cantilever end wall and into the closed-off distal portion; and

a plunger received in the rear opening of the handle and configured to move relative to the handle, the plunger being connected to the proximal end of the stylet.

12. The marking apparatus of claim 11, wherein a portion of the stylet including the distal end includes an angled surface, the distal end of the stylet being configured to engage the cantilever end wall when the stylet is latched in the expelled position.

13. The marking apparatus of claim 11, wherein a portion of the stylet including the distal end includes a ramp, wherein when the distal end of the stylet is moved toward the expelled position to close off the lateral opening of the cannula, the cantilever end wall is deflected by the ramp.

14. The marking apparatus of claim 11, wherein the handle has a detent, and the plunger has a catch configured to selectively engage the detent of the handle to latch the stylet in the extended position.

* * * * *